

movement of a lower extremity and method for manufacturing the same. The orthosis is fabricated by forming a positive mold of the lower extremity, and modifying the positive mold in predetermined locations to accomplish the type of lower extremity control desired.

[7] None of the above recited prior art patents either teach nor disclose the subject invention D-DAFO dynamic ankle foot orthosis and are essentially static rigid and molded support members and do not provide D-DAFO's "dynamic stability" uniqueness to hold the patient in STN (sub-talar) neutral while simultaneously maintaining tone and extension synergy.

SUMMARY OF THE INVENTION

[8] The present DeRoos DAFO invention overcomes the limitations and disadvantages of the prior art static orthosis by correcting misalignment of the bones of the foot and the involved joints dynamically while providing function and comfort to the patient.

[9] The orthosis is and has been utilized in clinical research with children diagnosed with cerebral palsy and other neurological pathologies where spasticity is involved. Utilizing conventional orthosis has been difficult with this population because the orthosis were of static force systems. The critical STN may be achieved with these conventional rigid static systems, but wearing compliance, comfort, and tissue breakdown were of constant issue. Few of the patients would comfortably tolerate the objectionable static holding forces.

[10] The results have been remarkable with the dynamic corrected force system with the D-DAFO. The D-DAFO works with circumferential support and dynamic stabilizing forces with the ability to increase or decrease with changes in incremental volume and overriding forces exhibited by the patient's spasticity. The elastic webbing and flexible plastics provide a supporting orthosis with a dynamic memory. The dynamics of the orthosis's supporting memory provides the necessary forces to maintain STN (sub-talar neutral) and corrected lower extremity alignment. This dynamic resistance moves with the patient to the point of malalignment limit and then returns the patient to the ideal STN position or the improved alignment for function.

[11] The D-DAFO dynamic support system restricts the patient from planter flexion. Planter flexion is a normal position when the foot is flexed downward. A spastic contracture of the posterior tibial (calf) muscles can hold the foot in that position and produce a shortening of the heel cord. This shortened heel cord can generate additional undesirable positions which can lead to permanent deformity if not treated properly with corrective orthosis, or surgery. Because children are malleable, they can usually be reshaped (molded) even though they may be twisted, turned and out of alignment from spastic contractures. These conditions are much more favorably correctable with the D-DAFO dynamic ankle support system as opposed to the conventional static systems of the prior art!

[12] Spasticity is commonly described as unwanted motor responses. It occurs because the inhibition normally provided by the brain suppressor areas is not present. Brain lesions disrupt the pathway to the muscles and create hyperactive phasic stretch reflexes, hyperactive tonic reflexes, and clonus, commonly referred to as "tone." The D-DAFO is utilized as a tone reducer and protects the patient from unwanted motion. The orthosis moves with the patient, yet supports and comfortably returns the patient to STN (sub-talar neutral), thus preventing unwanted posture positioning. The D-DAFO is dynamically working to maintain corrected alignment of the foot and ankle and while continuously supporting the STN position. By maintaining this ideal foot and ankle position during the growing years of children, deformities can be prevented and normal morphology and function can be obtained into adulthood. The D-DAFO continuously provides the support to hold the patient in STN yet the freedom to accommodate for high tone and extension synergy unlike conventional orthoses.

BRIEF DESCRIPTION OF THE DRAWINGS

[13] FIG. 1 shows a perspective assembled view of the dynamic foot orthosis including the posterior base shell (7) with upper and lower external flanges (15) & (16), fore-foot metatarsal posting (17), and hind foot posting (18) disposed at the bottom of the posterior base shell (7), tongue (9), Velcro strap (11), elastic Velcro strap (12), and attachment fasteners (13) oriented about the vertical axis (4) and the horizontal axis (5).

[14] FIG. 2 shows a plaster model of the subject patient's foot (14) that is insertable into the D-DAFO assembly, FIG 1, for mock-up and sizing.

[15] FIG. 3 is an exploded assembled view of the D-DAFO orthosis also showing the posterior shell (7), an outer anterior pre-tibial shell (8), tongue (9), liner (10), reinforcement (19), Velcro strap (11), elastic strap (12), attachment fasteners (13), and flanges (15) & (16).

[16] FIGS. 4 & 5 show a plan view representation of the D-DAFO with the Velco strap (11), and elastic strap (12) with a cross-section of the inner linings of the orthosis posterior and pre-tibial shell.

DETAILED DESCRIPTION OF THE PREFERRED EMBODIMENT

[17] The D-DAFO (DeRoos- Dynamic Ankle Foot Orthosis) as generally represented in the subject invention and further defined by the preferred embodiment in FIGS. 1, 3 and comprises a posterior base shell (7), an outer anterior (pre-tibial) shell (8) having an inside surface and an outside surface, the inside surface of the outer anterior pre-tibial shell is attached to an

outside surface of an upper portion of a tongue (9), tongue (9) is adapted to cover an anterior portion at a lower leg and adapted to cover a top portion of a foot of a wearer, a liner (10), Velcro strap (11), an elastic Velcro strap (12), and attachment fasteners (13).

[18] The posterior shell (7) is composed of TPE or similar polymer of nature providing a flexible yet stable shape. TPE is the most desirable with its blend of rubber and polyethylene plastic, giving it rigidity without brittleness. The posterior shell (7) is open on the front vertically and horizontally. The horizontal opening proceeds to the ankle axis in a wedge shape to allow for dorsiflexion and to allow the tibia to rotate. The vertical openings allow for donning and doffing. These openings of the posterior shell (7) create two pairs of upper and lower external flanges (15) and (16). The flanges (15) and (16) are flexible yet hold their shape to allow the proximal (upper) half of the tongue (9) and pre-tibial shell (8) to go forward pushing the upper (proximal) flanges (15) open. The pre-tibial shell (8) and tongue (9) is prevented from going out of the base shell by the flanges (15) and (16) memory and the elastic proximal (upper) strap (12). The pre-tibial shell (8) is preferred to be formed from Kydex.

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[19] The posterior base shell (7) includes an upper tibia portion with a front and back portion disposed about a vertical axis, and a lower ankle forefoot portion with a top and bottom portion disposed about a horizontal axis of patient's foot.

The posterior base shell (7) further includes a forefoot posting (17) and a hindfoot posting (18) at the bottom of the posterior base shell (7) for stability.

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[20] The thickness of the plastic TPE creates the resistance force on the pre-tibial shell (8) with the aid of the elastic Velcro strap (11). The thickness is determined by the size and weight of the patient. The Velcro strap (11) may be tightened to increase or decrease the support at the ankle and tibia. The tongue (9) and pre-tibial shell (8) provide a unique forward and backward movement. This movement of the top half of the tongue (9) (at the ankle axis) and pretibial shell (8) create the foundation of the D-DAFO's uniqueness giving it "dynamic stability." These dynamics allow the patient's tibia to rotate forward (anteriorly) and yet supported. The D-DAFO continuously provides the support to hold the patient in STN (sub-talar neutral) while simultaneously maintaining tone and extension synergy.

[21] The upper flanges (15) have an inside surface and an outside surface, said upper flanges (15) extending forwardly from a lower tibia portion of the posterior base shell (7) and adapted for covering and supporting the ankle area of a wearer, wherein when said orthosis is worn by a wearer, the outside surface of the outer anterior shell (8) is positioned to contact directly with the inside surface of the upper flanges (15), and the elastic strap (12) is positioned to cover the outside surface of the upper flanges (15).

[22] Other modifications not explicitly mentioned herein are also possible and within the scope of the present invention. It is the following claims, including all equivalents, which define the scope of the present invention.